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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,088	12/05/2001	John W. Sliwa JR.	003-007-C5	2423

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,088

Applicant(s)

SLIWA ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 92-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 92-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Applicant's amendments and comments, received October 29, 2004, have been fully considered by the examiner. The amendment to remove recitation of the generally cylindrical shaped transducer has obviated the objection to the drawings and 35 USC 112, first paragraph issues. The following is a complete response to the October 29, 2004 communication.

Specification

The disclosure is objected to because of the following informalities: the data in the "Cross Reference to Related Applications" should be updated, including patent numbers for those applications which have issued as US Patents.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 92-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acker et al ('084) in view of the teaching of Maguire et al ('288).

It is noted that the Acker et al device has an earliest filing date of March 24, 2000 based on priority to Provisional Application No. 60/192,074. Applicant's earliest prior application which includes support for the subject matter set forth in the instantly pending claims is US Serial No. 09/614,991 filed July 12, 2000. Hence the Acker et al

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patent is deemed to have an earlier priority date. Similarly, Maguire et al ('288) has a priority date of May 16, 2000.

Acker et al disclose a device for ablating tissue which comprises a body (10) which forms a loop structure. A plurality of ablating elements (26) is located on the body, each ablating element comprising an emitter of focused ultrasound energy (col. 4, line 36+). Acker et al specifically teach that each element may have a separate focal length, and that the focal length may be varied through tissue (col. 4, lines 60-67). The only features not expressly taught by Acker et al are the specific focal length and focal angle created by a curved ultrasonic transducer.

It is the examiner's position that the particular focal length and focal angle employed by the device would be inherently related to the tissue being treated and would therefore be an obvious operating parameter associated with the system in a given procedure. More particularly, the location and thickness of the tissue being treated would govern the necessary operating parameters and one of ordinary skill in the art would obvious recognize the necessary operating parameters for the procedure. Further, Maguire et al disclose an analogous ultrasonic ablation catheter which employs a series of transducers for ablating tissue. In particular, Maguire et al teach that the ablation transducers (830 – Figure 19b) may be provided with a curved surface to adjust the focal length of the device for treating a particular depth of tissue. See also column 46, lines 24+ of the Maguire et al reference. It is noted that the Maguire et al transducer (830) does not appear to be “generally cylindrical”, but does have the same structure as the curved transducer shown in Figures 59-61 of applicant's specification.

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To have provided the Acker et al device with transducers having a curved face to provide a desired focal length for treating tissue to a specific depth would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Maguire et al.

Claims 92-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins et al ('199) in view of the teachings of Sanghvi et al ('692).

Jenkins et al discloses an ablation apparatus which includes a loop-shaped body having a plurality of ablation elements located thereon. Jenkins et al teach that the ablation elements are preferably RF electrodes, but also teach that the ablation elements may be ultrasonic transducers (col. 15, lines 20-26). Jenkins et al fail to disclose the specific type of ultrasonic transducers (i.e. focused).

Sanghvi et al teach of the known use of focused ultrasonic transducers for the ablation of tissue within the body. In particular, the focusing of the transducer allows a particular tissue to be targeted at a particular depth. Also, the Sanghvi et al transducers are curved (Figure 2, surface 190) to control the focal length of the focused energy.

The examiner again maintains that one of ordinary skill in the art would obviously recognize the necessary focal length and focal angle which would be associated with a given procedure. Further, it also seems apparent that the Sanghvi et al transducers which have a curved surface may also be generally cylindrical.

To have provided the Jenkins et al device with a plurality of focused ultrasound energy emitters having a curved surface to target specific tissue and tissue depths for

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treatment would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Sanghvi et al.

Response to Arguments

Applicant's arguments with respect to claims 92-95 have been considered but are not deemed persuasive.

Applicant contends that the neither Acker nor Maguire disclose or suggest a "body adapted to be positioned around a tissue structure to be ablated, the body forming a loop structure adapted to be placed around the tissue structure to be ablated" and wherein the ablating elements direct focused ultrasound energy inward relative to the loop structure. In support of this assertion, applicant suggests that both the Acker and Maguire references are used for endovascular or endocardial ablation and, therefore, direct focused ultrasound radially outward.

It is the examiner's position that the statement of focusing energy inwardly relative to the loop structure is a recitation of intended use. Acker discloses a loop structure which is flexible in all planes and is therefore structurally capable of forming the loop in any desired configuration. That the Acker reference is preferably used in endovascular and endocardial procedures does not preclude the structure from being able to create a loop with the energy elements facing inward of the loop. As such, the examiner maintains that the Acker device is inherently capable of forming a loop with inwardly disposed ablating elements as set forth in the claims.

Similarly, the Jenkins loop structure also contains a steering assembly which would allow for the steering of the loop member in any direction. That is, the loop may

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be formed such that the energy emitting portions radiate inwardly. Again, it is the examiner's position that the Jenkins device is inherently capable of forming a loop with inwardly disposed ablating elements. The rejections are maintained and made final.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

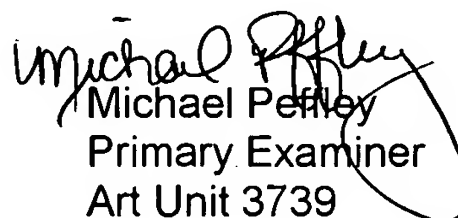
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Petley
Primary Examiner
Art Unit 3739

mp
December 16, 2004